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Development, evaluation, and overview of standardized training phantoms for abdominal ultrasound-guided interventions

Entwicklung und Evaluation von Trainingsphantomen für ultraschallgeführte Interventionen im Abdomen

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ABSTRACT

Purpose Ultrasound (US) represents the primary approach for abdominal diagnosis and is regularly used to guide diagnostic and therapeutic interventions (INVUS). Due to possible serious INVUS complications, structured training concepts are required. Phantoms can facilitate teaching, but their use is currently restricted by complex manufacturing and short durability of the materials. Hence, the aim of this study was the development and evaluation of an optimized abdominal INVUS phantom.

Materials and Methods Phantom requirements were defined in a structured research process: Skin-like surface texture, homogeneous matrix with realistic tissue properties, implementation of lesions and abscess cavities in different sizes and depths as well as a modular production process allowing for customized layouts. The phantom prototypes were evaluated in certified ultrasound courses.

Results In accordance with the defined specifications, a new type of matrix was developed and cast in multiple layers including different target materials. The phantom structure is based on features of liver anatomy and includes solid focal lesions, vessels, and abscess formations. For a realistic biopsy procedure, ultrasound-proof material was additionally included to imitate bone. The evaluation was performed by US novices (n = 40) and experienced participants (n = 41). The majority (73/81) confirmed realistic visualization of the lesions. The 3 D impression was rated as "very good" in 64 % of cases (52/81) and good in 31 % (25/81). Overall, 86 % (70/81) of the participants certified high clinical relevance of the phantom.

Conclusion The presented INVUS phantom concept allows standardized and realistic training for interventions.

ZUSAMMENFASSUNG

Ziel Der Ultraschall (US) hat einen hohen Stellenwert in der Viszeralmedizin und wird häufig als primäre Bildgebung und zur Steuerung interventioneller Eingriffe (INVUS) eingesetzt. Aufgrund potenziell schwerwiegender Komplikationen ist ein strukturiertes INVUS-Training mit möglichst realitätsnahen Interventionsphantomen sinnvoll. Bisher ist deren Einsatz durch eine komplexe Herstellung und begrenzte Haltbarkeit limitiert. Ziel war daher die Entwicklung und Evaluation eines neuartigen abdominalen INVUS-Phantoms.

‡ These authors contributed equally.

Material und Methodik Die folgenden Anforderungen an das Phantom wurden im Vorfeld definiert: Hautähnliche Oberflächentextur, homogene Matrix mit realistischen Gewebeeigenschaften, Implementierung von Läsionen und Abszesshöhlen sowie ein modularer Herstellungsprozess. Die Phantome wurden in verschiedenen Ultraschallkursen evaluiert.

Ergebnis Gemäß den Anforderungen wurde eine neuartige Matrix entwickelt und in mehreren Lagen gegossen. Die Phantomstruktur umfasst fokale Läsionen, Gefäße und Abszessformationen. Für einen möglichst realistischen Interventionsablauf wurde zusätzlich ultraschalldichtes Material als Imitierung von Rippen eingegossen. Die Bewertung wurde von im INVUS ungeübten (n = 40) und erfahrenen Ultraschallern (n = 41) durchgeführt. Die Mehrheit der Teilnehmer (73/81) bestätigte eine realistische Visualisierung der Läsionen. Der 3 D-Eindruck wurde von 64 % (52/81) der Teilnehmer als „sehr gut" und von 31 % (25/81) als „gut" bewertet. Insgesamt bescheinigten 86 % (70/81) der Teilnehmer dem Phantom eine hohe klinische Relevanz.

Schlussfolgerung Das vorgestellte INVUS-Phantom ermöglicht ein standardisiertes und realistisches Training von ultraschallgestützten Eingriffen.

Introduction

Ultrasound-guided interventions (INVUS) represent an integral part of modern medical diagnosis and therapy and range from simple needle visualization for vascular access, tumor biopsies, and complex drainage procedures to ultrasound-guided tumor ablation [1]. The key advantage of ultrasound-guided interventions is the continuous real-time visualization of the procedure in order to avoid vessels and other vulnerable structures [2]. This reduces the risk of life-threatening bleeding, nerve damage, and organ injury [3].

Ultrasound-guided interventions are frequently performed "free-hand" by applying one of the two basic principles of needle visualization (in-plane puncture with continuous visualization of the needle tip; out-of-plane puncture with better visualization of surrounding tissue). For complex approaches of small or profound lesions, modern ultrasound transducers offer dedicated devices for needle guidance and special transducers with integrated needle channels.

For safe and efficient INVUS procedures, the examiner needs profound knowledge of the applied material, sufficient spatial comprehension of the B-mode images, and a fundamental understanding of the hygienic handling of puncture instruments as suggested by the recommendations [4, 5]. Training with INVUS phantoms can improve workflows and thus reduce the interventional risk for the patient. Hands-on training on ultrasound phantoms is highly recommended by the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) before or complementary to the use on patients [2]. Even though the data on simulation-based training is rather limited, we are convinced that training improves skills in ultrasound-guided procedures [6]. INVUS phantoms require a realistic ultrasound imaging appearance and haptic properties as well as attenuation and backscatter patterns comparable to human tissue. In addition to the echo texture, these phantoms must also reproduce the mechanical properties and interactions of the phantom matrix and the intervention tool as best as possible. Especially the latter cannot be replaced by any kind of virtual training.

Currently available training modules range from matrix phantoms, mostly agar-, gelatin- or silicone-based, which are mainly used in small training groups, to highly complex and cost-intensive simulations focusing on the cannulation of vessels. However, the widespread application of INVUS phantom-based training is limited by rather simple haptic and imaging properties, short matrix stability, as well as cost.

To overcome these limitations, we summarized the current available data on ultrasound INVUS phantoms and developed and evaluated a training module prototype that would combine three essential aspects of a puncture phantom: a standardized and efficient production process, realistic haptic impression and image morphology, and reusability for complex use even in larger groups.

Review of currently available INVUS phantoms

From the end of the late 1980 s, training phantoms began to become established primarily for training ultrasound-guided vascular punctures, but simple phantoms were developed for biopsies as well [7, 8, 9]. In recent years, the range of phantoms for ultrasound-guided interventional procedures has expanded considerably. Currently, there are three major technical methods for ultrasound training phantoms: Training phantoms with animal tissue, e. g. cadavers, virtual reality simulators, and matrix-based phantoms which will be characterized in more detail below.

Matrix-based phantoms

Considerable evidence is available for phantoms based on variable matrices such as polymers polyvinyl alcohol (PVA), polyvinyl chloride (PVC), gelatine, silicone, and agar [10, 11, 12] (▶ **Table 1**). These matrices are complemented by target structures (tube-like vascular models, solid lesions, and fluid-filled cavities) and range from homemade phantoms, i. e., models based on pastry or porridge mainly for personal use, to high-performance simulators [13].

Homemade phantoms

The advantages of non-commercial phantoms are their low cost and ability to be adapted to the user's wishes by combining a basic substance with a carrier solution. Individual material can be dedicated to transducer frequency, needle insertion behavior, mechanical feedback, and durability. The matrix structure can enclose target objects and obstacles. However, the aforementioned

▶ **Table 1** Phantom matrix material performance.

	Agar	Gelatine	PVC	Silicone
Speed of sound	+	+	0	–
Attenuation coefficient	+	+	0	–
Elasticity	–	+	+	0
Force of puncture	–	–	+	0
Friction	+	+	0	–
Durability	–	–	+	+

Overview of various matrix substances in terms of realism with respect to human tissue + = more realistic; 0 = neutral; – = more unrealistic

benefits are accompanied by time-consuming production and hygienic concerns that preclude commercial use.

Commercially available phantoms

Compared to self-produced phantoms, commercially manufactured phantoms, e. g., CAE Healthcare Blue Phantom (Sarasota, FL) and the Kyoto Kagaku CVC Insertion Simulator (Kyoto, Japan), offer better durability but are cost-intensive and therefore not consistently available and, unfortunately, as mentioned at the beginning, abdominal INVUS cannot be practiced. **Supplementary table 1** gives an overview of the currently available phantoms for ultrasound-guided interventions.

Polyvinyl alcohol (PVA) and polyvinyl chloride (PVC)

PVA and PVC are non-toxic synthetic polymers that have become increasingly important in recent years and show good results regarding the interaction between the puncture needle and tissues [14, 15, 16]. With appropriate mixing ratios of the matrix components and further additives, realistic sonic velocity and matrix elasticity can be achieved. Frequently used additives of PVA are sodium trimetaphosphate (STMP), dimethyl-sulphoxide (DMSO), NaCl, NaOH, and epichlorohydrin (ECH), whereas PVC relies on softener and lubricating agent, optical additives such as black plastic colorant (BPC), or acoustic additives by means of plastic hardener [17, 18, 19, 20, 21, 22]. The advantages of synthetic polymers are primarily their higher mechanical strength and very long durability. Unfortunately, phantoms made of synthetic PVA and PVC require a more complex manufacturing process [22]. In addition, the puncture channels remain visible, which also limits the duration of use. Furthermore, both PVA und PVC are not biodegradable.

Gelatine and agar materials

Gelatine and agar are natural products which are low-cost substances and are easy to process, hence they are frequently used for interventional phantoms. It is possible to create large-scale phantoms using gelatine or agar and these materials are therefore particularly suitable for phantoms to practice abscess drain insertions. Due to the production process using powder dissolved in different quantities of liquid, it is possible to generate areas with various degrees of echogenicity. However, it is difficult to mimic muscles or fascia structures [23], and durability is restricted by rapid liquefaction at room temperature and infestation of molds due to contamination during production or usage [12, 24].

Silicone

Silicone, a non-toxic inorganic material, is also frequently used as a basic matric for interventional phantoms [25]. Silicone has limited acoustic properties and is anechoic. Therefore, modifications such as the admixture of glass dust is necessary for realistic imaging [25, 26]. The advantage of silicone is its longer sustainability compared to water-based materials. Unfortunately, silicone is a firm material and requires non-physiological forces during puncture processes. Lubricants such as paraffin oils are often used to mitigate these issues.

Hybrid phantoms

Hybrid models consist of different materials of the methods that were presented so far. For example, a gelatine-based phantom is selected due to the realistic echogenicity and silicone matrix is used as the top layer to imitate human skin. Cadaver materials may also be integrated into such matrix-based phantoms. This approach allows good image features of the surrounding tissue and achieves realistic mechanical feedback. However, the advantages of implemented biological structures are often reduced by low durability [27].

Phantom development and results

i) Demands regarding an abdominal ultrasound phantom for interventions

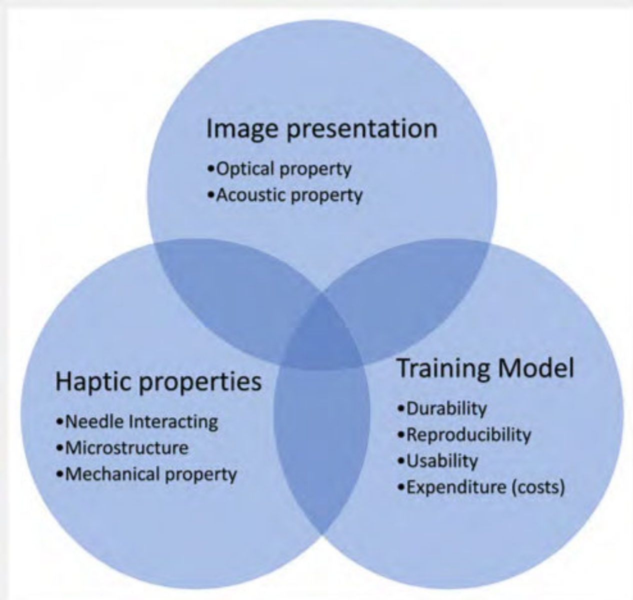
The requirements for an abdominal phantom for interventions are varied and should take different conditions into account (see ▶ **Fig. 1**):

Tissue mimicking

A homogeneous matrix with medium echogenicity clearly demarcating the target lesion by increased echogenicity is preferable. The optical properties should have a good absorption coefficient and, preferably, a reduced scattering coefficient. The acoustic properties should be similar to human tissue in terms of speed of sound, attenuation, and backscatter coefficient, to achieve good acoustic quality and proper visualization.

Needle visualization and interaction

Properties of elasticity, shear forces, and rigidity play an important role in a realistic simulation and are primarily determined by the polymer structure and its pore size. Cutting and frictional forces are essential determinants for a simulation that is close to



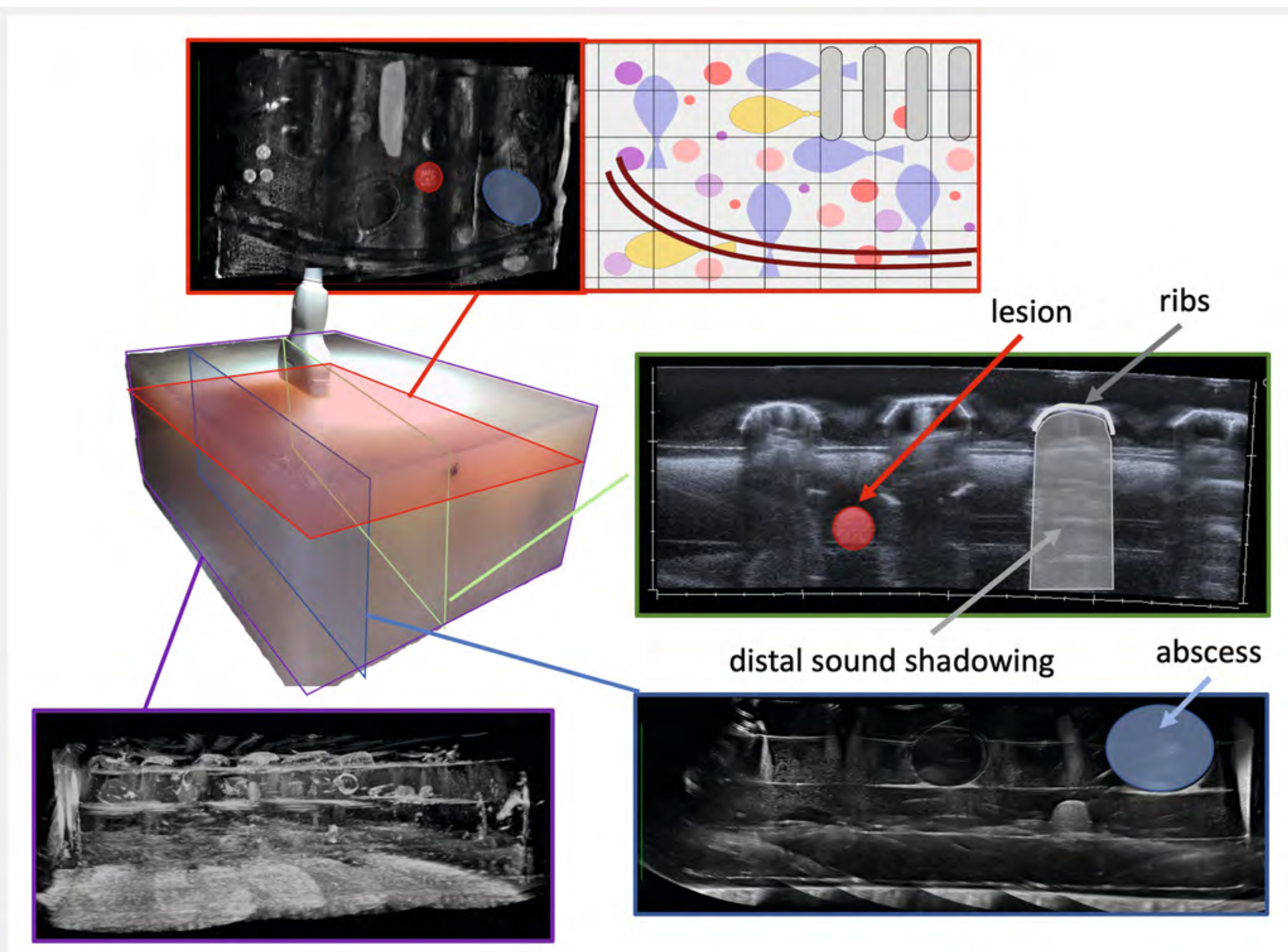
▶ **Fig. 1** Key requirements for an INVUS phantom.

reality and human tissue. Moreover, the puncture channel should be "closed" sufficiently without leaving a visible puncture line.

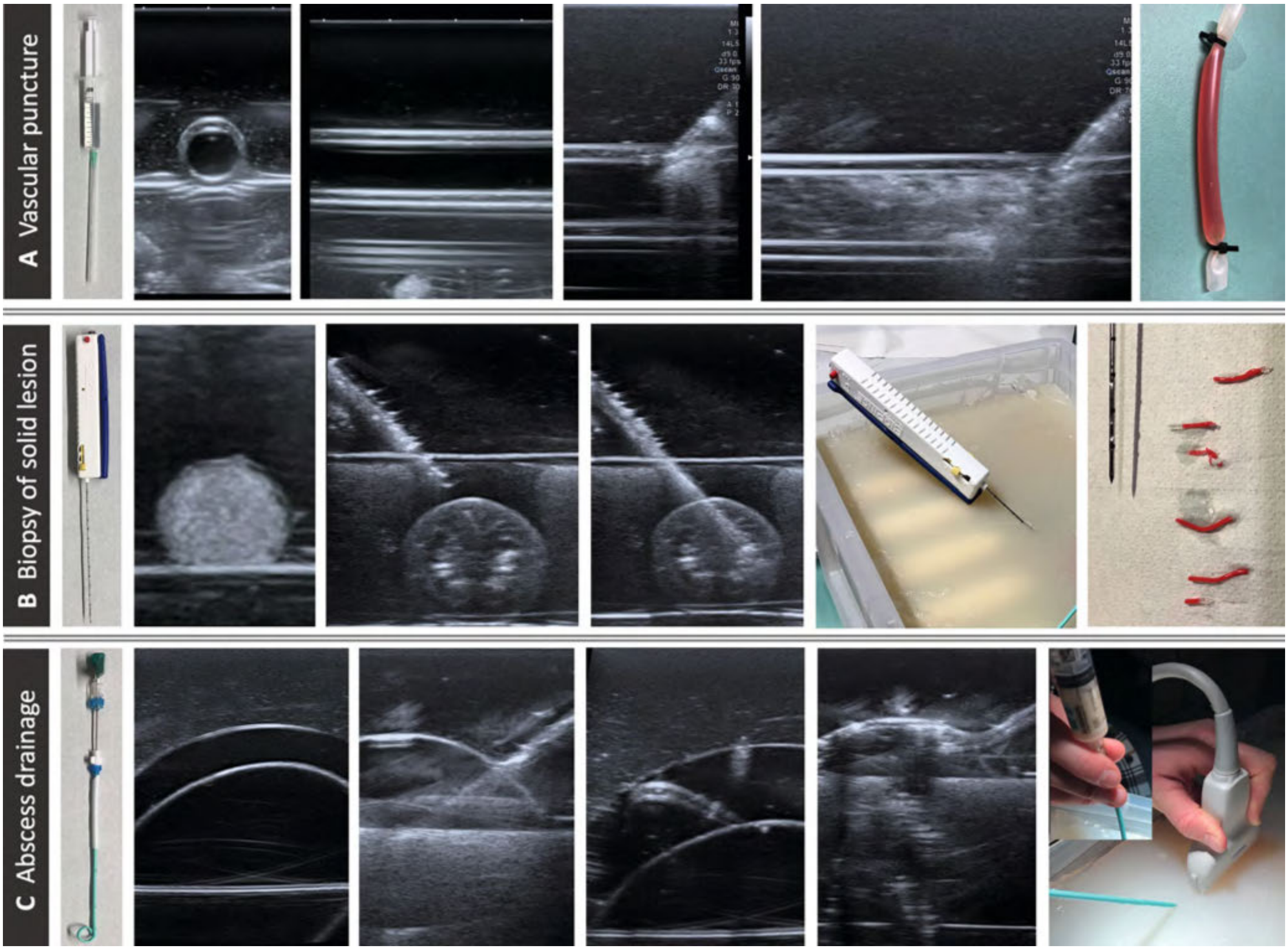
Requirements as a training module

The phantom to be developed is intended to fill the gap between short-lived homemade models and cost-intensive elaborate simulators. The requirements here are obvious: An orderable modular system (see **Supplementary Figure 1**) that can be assembled according to the wishes of the consumer and is usable over a longer period of time. Reproducibility and application for larger group sessions were desired. At the same time, the aim was to develop a modular design that allows for training in different scenarios and puncture techniques, including the insertion of drains and biopsy sampling. This design sought to incorporate vessels, liquid abscesses, and solid lesions, all color-coded for efficient visual monitoring during procedures like drainage or biopsies.

A range of requirements and levels of difficulty, made possible by obstacles such as existing ribs, allows even advanced users to continue practicing. Draining procedures and stitching channels should not trigger disturbing and limiting sound reflexes after the first attempt.



▶ **Fig. 2** Three-dimensional ultrasound visualization of the intervention phantom.



► **Fig. 3** Examples of ultrasound-guided interventions: **A**) Vascular canaliculation using the in-plane technique, **B**) biopsy of a solid target lesion, **C**) insertion of a drainage catheter.

ii) Production process

An approach corresponding to the requirements profile and specific advantages of the materials listed in ► **Table 1** was developed in multiple experimental series. The Forschungszentrum Ultraschall gGmbH provided its expertise and took a leading role in the development.

Matrix

Agar was used as the matrix material because of the aforementioned properties (sound velocity similar to 1540 m/s, low sound attenuation). An agar-water mixture in a ratio of 3 g agar to 200 ml water was used. Boiled mixture was poured in multiple layers into a stable, open-top rectangular plastic container. Upon cooling, the mass solidifies, and the puncture targets can be placed on the respective layer and another matrix layer can be poured over it. Typically, four agar layers are used.

Lesions and abscesses

Target structures for biopsy are designed as agar spheres with diameters ranging from 1.5 cm to 2.5 cm depending on the desired level of difficulty. The agar-water mixture used for their preparation contained slightly more agar than that used for the matrix, and red color pigment was added to increase the sonographic contrast with the matrix and allow easy visual feedback regarding the success of the biopsy (see ► **Fig. 2**, ► **Fig. 3**, ► **Fig. 4** and **Supplementary Figure 1**).

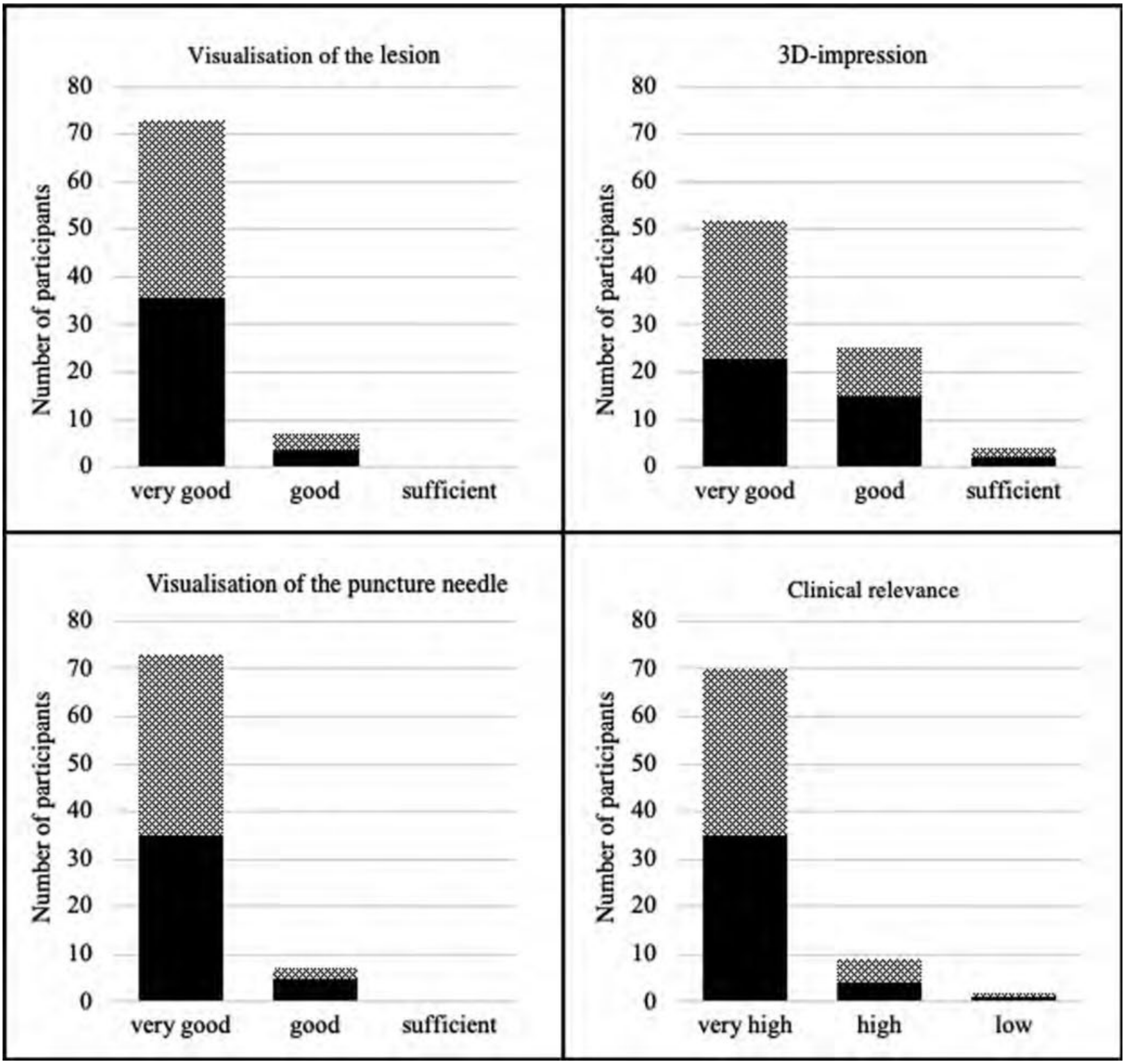
Abscess simulations can be used to practice the placement of drains. They are designed as liquid-filled latex balloons of different sizes.

Blood vessels

The reproductions of blood vessels were placed superficially. To achieve a sufficiently realistic imitation of the different anatomy of arteries and veins, silicone tubes with varying wall thicknesses (0.5–1 mm) and different internal diameters (5–10 mm) were used (see ► **Fig. 3** and **Supplementary Figure 1**). Flow characteristics may be generated by connection with an external fluid pump.

Bone structures

Bones represent a natural obstacle to INVUS procedures. Here, we simulated ribs that were placed in the matrix (see ► **Fig. 2**). They were made of epoxy resin cast in a rib-like shape and withstand



▶ **Fig. 4** Assessment of the phantom in terms of “visualization of the lesion”, “3 D impression”, “visualization of the puncture needle” and “clinical relevance” by novices (grey) and experienced participants (black).

needle puncture forces. These bone structures provide significant ultrasound attenuation and limit the visualization of the phantom area underneath. This allows for practical training in the positioning and orientation of the ultrasound probe and puncture needle.

Fat layer and skin

The agar matrix is too delicate for the application of especially curved array transducers. Therefore, the surface of the phantom is built by a replicated layer of fat and skin, which allows better adaptation of haptic feedback to the human body surface. The fat layer was made using the FlexUS material [28]. This material is highly elastic, weakly echogenic, and has low sound attenuation, while the skin layer consists primarily of a stiffer latex or silicone layer, which has significantly increased mechanical resistance in order to provide good haptic feedback.

Properties

By adding preservatives, the potential shelf life of the agar matrix is increased by up to 6 weeks. However, it has been shown that a major advantage of the developed phantom is its modularity. Depending on the requirement profile of a training course, different configurations of puncture targets and ribs can be implemented as obstacles. The manufacturing process presently requires approximately 12 hours and is predominantly conducted manually.

iii) Evaluation of the abdominal training phantom

To evaluate usability, training effect, and handling, the phantom was used in two different medical user groups with different levels of expertise in interventional ultrasound (Group A: 40 novice training; Group B: 41 dedicated interventional training, postgraduates [29]) and participants were surveyed using a standardized questionnaire. Written consent was obtained from all participants. Both groups received a short introduction to the phantom and the available interventional material. A standard biopsy procedure of a focal lesion as well as drainage of an abscess cavity were demonstrated by an expert trainer. Directly after the standardized training introduction, the participants performed target punctures by themselves (5 minutes per participant). Afterwards, the participants provided an evaluation using a standardized questionnaire, addressing their ultrasound experience and level of education as well as their impression of the interventional training scenario based on ordinal scales ranging from "1" very good to "5" very poor. (**Supplementary table 2**).

Among the two groups, 36 participants were within the first 3 years of their medical training, 14 participants were in advanced medical training, and 29 participants were already residents.

The overall impression of the interventional training scenario was very good (Group A: 1.03 ± 0.16; Group B: 1.28 ± 0.45) and the majority of the participants described the puncture experience as realistic (Group A: 1.45 ± 0.63; Group B: 1.39 ± 0.54). In addition, the ultrasound visualization of the embedded materials, the needle tracking, and the clinical relevance were also judged as satisfactory (▶ **Fig. 4**).

Discussion

Interventional ultrasound has become an essential part of modern medicine and is nowadays not only used as a tool for cannulating large vessels but has also become indispensable in the diagnosis of unclear lesions and the treatment of abdominal abscesses. Modern technical approaches also comprise ultrasound-guided tumor ablation therapy. However, such complex procedures require standardized training concepts to guarantee successful and safe interventions. To bridge the gap between theory and practice, interventional phantoms – realistic simulations of anatomical and pathological structures – are increasingly used [2]. Phantoms for interventional ultrasound training, apart from VR simulations, are mainly based on a solid gel base with inserted interventional units and range from "homemade" simulators with a short lifespan and insufficient puncture properties to highly sophisticated models with a realistic intervention experience.

The aim of this study was the development of a realistic phantom for abdominal interventions that combines both the advantages of homemade phantoms and the benefits of commercially available phantoms. The phantom should be as realistic as possible in terms of image impression using regular ultrasound equipment and the haptic feeling using regular biopsy systems.

One of the major challenges when developing a phantom for interventional training is its repetitive usage by many investigators. An interventional phantom should last at least the time of a regular ultrasound course without relevant destruction and should be equally good for all examiners in terms of both consistency and image impression. Particular attention should be paid to the disappearance of the needle channel after removal of the needle, so that interference due to old needle channels is reduced to a minimum (see **Supplementary Figure 2**). At the same time, the haptic sensation during both the insertion and the passage of the needle through the phantom must resemble the human body and should also allow a tissue sample to be generated during a biopsy procedure. Classic self-made phantoms differ in this regard significantly from higher-quality products, due to the high viscosity of lesions in simple phantoms, with the result that biopsy systems are slowed down too much during the sampling procedure so that no material can be obtained.

After a careful development process, including a precise definition of the requirements, in cooperation with an established research institution for ultrasound methods, it was possible to create an interventional phantom that largely meets our requirements. The phantom consists of an agar matrix and is modularly equipped with different target lesions, imitation of vessels, and abscess formation. A significant advantage of this procedure is the standardized production even in larger quantities and at the same time it is individually adaptable. However, the durability of this novel phantom is also limited. Nevertheless several components (e. g., fat layer, ribs) can be repurposed.

There is still need for further development like liquid/cystic formation, particularly in the case of abscess cavities, as the cavity collapses after a single puncture of the fluid-filled cavities, making repeated drain insertion only possible to a limited extent. Phantoms serve to simulate reality and therefore, by definition, cannot perfectly depict reality, which is also the case for our phantom. In the end, a phantom, including our phantom, serves as an access point for the multifaceted reality of the clinical routine.

The interventional phantom was evaluated in different ultrasound courses by investigators inexperienced in ultrasound-guided interventions as well as examiners with expert knowledge in the field of ultrasound. Both cohorts were impressed by the realistic simulation of interventions and the clear visualization of the needle. After a standardized short introduction, all participants were able to perform ultrasound-guided investigations on their own in a safe training scenario.

In conclusion, it was possible to develop a quite realistic phantom for ultrasound-guided interventional usage that fulfills both the conditions of repetitive usage and a cost-saving production process. Ultrasound-guided interventions will be increasingly in demand in the future and, due to their potentially life-threatening complications, training in different scenarios is urgently needed before clinical use. In contrast to learning an examination procedure e. g., examination of the liver, intervention exercises cannot be purely virtual, but require exposure to real intervention material in an environment that is as realistic as possible. After training on puncture phantoms, punctures in low-risk indications (e. g., ascites draining) can be practiced. Certainly, after an extensive test phase, our phantom should be evaluated with existing and evolving homemade phantoms to ensure steady progress and better realism.

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Conflict of Interest

Sabine Kern, Ralf Steinhausen and Jana Klammer are employed at the Research Center for Ultrasound gGmbH and were involved in the development of the ultrasound phantom. The research center is a non-commercial, non-profit organization. The remaining authors are not financially involved in the development of the phantom and have no conflict of interest.

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